

BEFORE THE ALTERNATIVE HEALTH CARE BOARD
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of)	NOTICE OF AMENDMENT AND
ARM 24.111.511 naturopathic)	ADOPTION
physician formulary and the adoption)	
of NEW RULE I military training or)	
experience)	

TO: All Concerned Persons

1. On April 10, 2014, the Alternative Health Care Board (board) published MAR Notice No. 24-111-25 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 645 of the 2014 Montana Administrative Register, Issue No. 7.

2. On May 1, 2014, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Several comments were received by the May 9, 2014, deadline.

3. The board has thoroughly considered the comments received. A summary of the comments received and the board's responses are as follows:

CHANGES TO FORMULARY/ARM 24.111.511:

COMMENT 1: The Montana Board of Medical Examiners (BOME) opposed the addition of the five substances to the formulary rule, asserting they are potentially dangerous substances which often require a high level of training and expertise on the part of the prescriber.

RESPONSE 1: The board agrees that Naturopathic Physicians (NDs) must have sufficient training and expertise before prescribing any substance.

The board notes that, while there are some part-time, online, and correspondence schools that purport to award naturopathic doctor degrees, the graduates of these schools are not eligible for licensure in Montana as NDs. Montana-licensed NDs must complete a comprehensive course of study at an approved four-year naturopathic medical college and pass a rigorous professional examination. See 37-26-402, MCA. Approved naturopathic medical colleges are graduate schools that are accredited by the Council on Naturopathic Medical Education (CNME), which is a member of the Association of Specialized and Professional Accreditors (ASPC). The ASPC includes the programmatic accreditors recognized by the U.S. Department of Education and its members include the accreditors for allopathic/medical (MD), osteopathic (DO), chiropractic (DC), acupuncture, and dental programs.

The general educational structure is similar for ND and MD students. The first year emphasizes biomedical sciences, such as anatomy and biochemistry, and

the second year emphasizes the diagnostic sciences, including areas like evidence-based medicine and physiological assessment. During the first two years, ND and MD students have almost identical credit loads. A 2010 course comparison of the University of Washington's (UW) MD program and Bastyr University's ND program showed that the UW MD students completed 150 credits and the Bastyr ND students completed 151.5 credits in comparable biomedical and diagnostic science courses.

While a majority of MD students opt for careers in specialties, i.e., oncology, and pursue the requisite specialized education and training, all ND students are training to become primary care physicians. ND students learn to recognize the symptoms of diseases that fall outside of their scope of practice, i.e., cancer, to refer patients to specialists as appropriate. While some practicing NDs do expand their education and develop specialty areas, the focus of naturopathic medical school is identifying and treating diseases that fall within the realm of general practice.

Pharmacology education is required for all ND students. See 37-26-103(1), MCA, and ARM 24.111.501. As of 2013, recognized programmatic accreditors, including the CNME, the Commission on Osteopathic College Accreditation, and the Liaison Committee on Medical Education, did not set specific standards for pharmacology education. The professional schools set their own pharmacology curriculum. A comparative analysis in 1997 of MD, DO, and ND pharmacology curriculum found that MDs complete 114 credits, DOs complete 108 credits, and NDs complete 100 credits.

Accredited naturopathic medical schools provide instruction on basic principles of pharmacology including clinical indications, main mechanisms of action, and the chief side effects of prototypical drugs of each of the major contemporary drug classes. Students are expected to be able to predict the chief therapeutic effects and chief side effects. In specialty courses such as cardiology, gastroenterology, gynecology, and endocrinology, students are taught the therapeutic options for specific conditions and trained in the broadest national scope of practice for an ND which includes both naturopathic and allopathic care including surgical and pharmacological options. All this is reinforced during clinical experience as many patients come to NDs with pharmaceuticals already in place requiring knowledge regarding the clinical implications.

The Naturopathic Physicians Licensing Exam (NPLEX), required for licensure, tests applicants' knowledge of pharmacology. Specifically, Part II of the NPLEX, the Core Clinical Science Examination, is a case-based, integrated test of clinical competency requiring knowledge of: pharmacology of commonly prescribed drugs; primary actions, adverse effects, indications, contraindications, and potential interactions with botanical medicines, nutritional supplements, and other drugs; natural therapeutic interventions having effects similar to commonly prescribed pharmaceuticals; and monitoring and assessing therapeutic drug levels and toxicity.

NDs are licensed in 18 states and two U.S. territories and have prescribing rights in 13 states. The Drug Enforcement Administration (DEA) grants DEA numbers to licensed NDs with prescribing authority. While Montana uses a nonexclusive formulary list, Washington and Oregon recognize the education and training of NDs and do not restrict the prescribing authority of licensed NDs.

Additionally, Montana-licensed NDs are required to complete at least five hours of continuing education in pharmacology annually, which is a third of the

required continuing education, for license renewal. See ARM 24.111.2102. Montana-licensed NDs are well educated in pharmacology.

Addressing the patient safety concerns raised, the board notes that NCMIC, the largest malpractice insurer of licensed NDs, has not had a claim against an ND involving prescription medications as of 2010. A 2013 nationwide search by Verdict-Search also found no records of malpractice suits against NDs. Additionally, between 2002 and 2012, the National Practitioner Databank, maintained by the U.S. Department of Health and Human Services, had no records of malpractice claims against NDs. In 2011, Oregon, which has licensed NDs since 1927, acknowledged the extensive education and clinical training regarding pharmaceuticals and adopted an open formulary representing all legend drugs for NDs.

The U.S. Senate acknowledged the safety and effectiveness of naturopathic medicine by passing Senate Resolution 221 designating the week of October 7-13, 2013, as "Naturopathic Medicine Week" to "recognize the value of naturopathic medicine in providing safe, effective, and affordable health care." Specifically, Sen. Res. 221 stated that NDs complete four-year, graduate level programs that are accredited by agencies approved by the U.S. Department of Education and further noted that "naturopathic physicians can help address the shortage of primary care providers in the United States" and "are trained to refer patients to conventional physicians and specialists when necessary."

COMMENT 2: The Montana Pharmacy Association (MPA) commented that, while the formulary list is intended to clarify what medications a pharmacist can legally dispense pursuant to a prescription from a naturopathic physician, "the addition of these particular medications will only add to pharmacist confusion on why these medications are considered of natural origin and whether they can be legally dispensed." The MPA stated that, "[i]t will be unclear to pharmacists what the basis of inclusion will be and the use of these medication in naturopathic practice." The MPA further stated, "[w]e are concerned that the proposed changes may open the door for the addition of other synthetic derivatives in the future. If this happens pharmacists could be stuck in the middle when trying to bill claims to an insurance company or justifying the origin and validity of the prescription during an audit."

RESPONSE 2: The board is unclear on how specifically listing the five substances in the formulary list will confuse pharmacists. When presented with a prescription written by a ND, a pharmacist checking the formulary has clear guidance that a listed substance is within the ND's prescribing authority.

The five substances have a natural origin and were reviewed and approved to be listed in the formulary by the five-member alternative health care formulary committee (formulary committee). Under 37-26-301(3), MCA, the formulary committee, consisting of "a licensed pharmacist plus four members of the Board [of Alternative Health Care], two of whom must be licensed naturopathic physicians, one who must be a licensed medical doctor, and one who must be a public member," reviews the formulary at least annually. The formulary committee is responsible for ensuring that the formulary list does not exceed the scope of substances covered by approved naturopathic college curricula or continuing education and making recommendations to the board. The five substances were

reviewed by the formulary committee and found to meet the requirements of 37-26-301, MCA, to be specifically stated in the formulary list.

The board disagrees that specifically listing the five substances in the formulary "may open the door for the addition of other synthetic derivatives in the future" and that "pharmacists could be stuck in the middle when trying to bill claims to an insurance company or justifying the origin and validity of the prescription during an audit." The listing of a specific substance on the formulary list gives clear guidance to a pharmacist that the substance is within the naturopathic physician's prescribing authority. Whether a claim for a prescription written by a naturopathic physician is covered by an insurer will depend on the policy contract terms and the insurance regulatory system. See generally, Title 33, Mont. Code Ann., Insurance and Insurance Companies. However, the listing of a specific substance on the formulary list would seem to support a pharmacist seeking to get a claim paid or respond to an audit.

COMMENT 3: The Montana Medical Association (MMA) commented that the proposed additions to the formulary list inappropriately expand the scope of acceptable naturopathic formulary medications permitted under 37-26-301(3), MCA. The MMA stated that, "[o]ver 50% of all existing pharmaceuticals prescribed by fully trained and certified Medical Doctors are derived from a 'natural substance'" and that naturopathic physicians appear to be trying to "encompass all possible prescription medications derived from 'natural' sources" which "is not what was intended by the legislature when this statute was originally passed." The MMA further stated that including the five substances on the formulary presents a real and ongoing danger to the health of Montanans.

RESPONSE 3: The board disagrees. Montana-licensed NDs are primary health care providers who diagnose and treat human health conditions, injuries, and diseases. See 37-26-103(7), MCA. NDs have authority under 37-26-301, MCA, to prescribe pharmaceuticals with a natural basis in treating their patients. Each of the five substances has a natural basis. See the proposal notice in this matter, MAR Notice No. 24-111-25.

Section (3) of 37-26-301, MCA, provides that the formulary list "may not go beyond the scope of substances covered by approved naturopathic college curricula or continuing education." By the plain language of the statute, the Legislature intended that NDs prescribe substances for which they have received training and education. See Response 1 for more information regarding the education, training, and licensing of NDs.

The five substances were reviewed and approved by the alternative health care formulary committee to be specifically listed in the formulary. See Response 2 for more information regarding the formulary committee. Specifically listing the five substances does not expand the scope of the formulary as the formulary list in ARM 24.111.511 is nonexclusive. Each section broadly identifies a type of substance that may be administered, while the subsections contain examples, i.e., section (10) provides that NDs may prescribe and administer hormones, and its subsection (c) lists glucagon as an example.

Regarding the safety concerns raised, see Response 1 for information about the education, training, licensing, and patient safety record of NDs.

COMMENT 4: Numerous commenters asserted that insulin is a powerful hormone and that years of specialized training is required to learn how to prescribe it correctly. The MMA further commented that "some limited hours of education regarding the derivation and use of insulin in naturopathic school, or any amount of continuing education courses" does not adequately prepare a naturopathic physician to manage a diabetic patient with this drug. The MMA stated it was "inconceivable" that "any naturopath has achieved the level of training needed to treat diabetes effectively and comprehensibly in an individual" -- and especially for "management of childhood diabetes" -- with insulin and metformin. The MMA stated that insulin, metformin, and any diabetic medication should be prescribed by individuals who are fully trained to care for diabetes through "fully accredited post graduate medical training" and that "there are no facts presented that demonstrate naturopaths have the needed level of training for adequate safe and effective treatment of diabetes using prescription medications."

RESPONSE 4: Montana-licensed NDs are fully trained on proper assessment and diagnosis and know when to function as a primary care provider and when to refer patients to a specialist. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct to perform treatments or provide services beyond the provider's education, training, or licensure. See 37-1-316(18), MCA.

Insulin and metformin have a natural origin. Insulin is a hormone and metformin originated from French lily or goats' rue. Under 37-26-301, MCA, NDs may prescribe pharmaceuticals with a natural basis that are covered in their education and training. See Responses 1, 2, and 3 for more information regarding the education, training, licensure, and patient safety record of NDs, the formulary list, and the formulary committee.

Insulin and metformin were reviewed and approved by the formulary committee to be specifically stated examples in the formulary list. See Responses 2 and 3 regarding the formulary list and formulary committee.

COMMENT 5: The MMA commented that the board presented no facts that NDs receive adequate training and experience in the appropriate use of botox or of Juvederm in the treatment of dermatologic needs. The MMA further stated that, by suggesting that NDs are qualified to use these treatments based on their naturopathic college curricula or continuing education courses shows a lack of understanding of the seriousness of the use of these medications and underestimation of the level of training needed to use them safely and effectively.

RESPONSE 5: The board disagrees. See Response 1 for information regarding the education, training, licensing, and patient safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 6: Several commenters stated that metronidazole is a strong antibiotic and that "[t]rained and certified Medical Doctors spend literally years after their four years of medical school learning how to use antibiotics such as metronidazole." (Emphasis in the original.) The MMA stated that the appropriate use of antibiotics "cannot be learned from a course in any medical or naturopathic school" and that, "[t]o suggest that naturopathic curriculum includes adequate training for the use of metronidazole, or for that matter any antibiotic, shows a profound lack of awareness of the seriousness of appropriate use of antibiotics in this day and age." Additionally, the MMA stated that, "[t]here are no 'continuing education' courses available to any practitioner in any medical or naturopathic field which would adequately provide this level of needed knowledge."

RESPONSE 6: Montana-licensed NDs must first complete a comprehensive course of study at an approved naturopathic college which includes pharmacology and clinical education. See Response 1. Naturopathic students assume primary responsibility for patient care, under the supervision of licensed doctors, as soon as their third and fourth years of naturopathic college. The ND licensing exam, NPLEX, Part II tests applicants' knowledge of pharmacology and also clinical competency. See Response 1.

Antibiotics have been on the formulary list since its inception. As explained in Responses 2 and 3, the formulary list is nonexclusive and the alternative health care formulary committee has reviewed and recommended that metronidazole be specifically listed in the formulary to facilitate the ability of patients to fill prescriptions.

Like other primary care physicians, NDs can and do order clinical laboratory tests to identify the cause of an infection to avoid incorrectly prescribing an antibiotic such as metronidazole. See 37-26-301(4), MCA. Further, NDs have an excellent patient safety record as discussed in Response 1.

COMMENT 7: Several commenters opposed adding all five substances to the formulary, stating that naturopathic knowledge and training is inadequate to safely prescribe these substances for use in a therapeutic regimen. Some commenters stated that naturopaths are not trained to recognize and treat possible complications and side effects of these substances and that allowing naturopaths to prescribe these five substances places patients at risk for harm or death.

Commenters stated that physicians complete four years of college, four years of medical school, and three to six years of residency. Another commenter stated that naturopaths receive at best the equivalent of a four-year M.D. or D.O. student's training and that only one state, Utah, requires a one year residence.

Another commenter stated that many naturopaths migrate to the field because they do not have the credentials to attend medical school.

One commenter stated that there is a lack of accountability and credibility within naturopathic training. The effectiveness and standardization of NPLEX has been questioned. Further, the NPLEX "does not have a Step 3 portion of the exam testing clinical competency like the United States Medical Licensing Examination

(USMLE) does of M.D. students." Previously, the CNME lost its recognition by the U.S. Department of Education, but regained recognition in 2003.

One commenter stated that "naturopaths deny or are ignorant of the scientific reasoning and research upon which all of modern medicine is based."

One commenter stated that naturopathic medicine can be defined as a "pseudoscientific form of alternative medicine" which "favors a holistic approach with non-invasive treatment and generally avoids the use of surgery and drugs" and that practitioners "often prefer methods of treatment that are not compatible with evidence-based medicine, and in doing so, reject the tenets of biomedicine and modern science."

RESPONSE 7: Montana-licensed NDs complete a comprehensive course of study at an approved naturopathic college which includes pharmacology and clinical education. See Response 1 regarding the education, training, and licensing of NDs. NDs are trained to recognize and treat possible complications and side effects of pharmaceutical, herbs, and herb-drug interactions. See Response 1.

The board disagrees with the commenters that naturopathic medicine is pseudoscientific and the NDs shun evidence-based medicine and the tenets of biomedicine and modern science. The education and practice of Montana-licensed NDs is well-grounded in science and biomedicine. See Response 1.

Part II of the NPLEX is the Core Clinical Science Examination. It is a case-based, comprehensive test of clinical competency. See Response 1. Further, licensed NDs have an excellent patient safety record. See Response 1.

Since 2003, the CNME has been continuously recognized by the U.S. Department of Education as an accreditor of naturopathic medical colleges. The brief loss of recognition prior to reinstatement in 2003 is not relevant. Moreover, in 2010, the U.S. Department of Education reviewed the CNME and granted its longest recognition of five years to 2015.

Naturopathic medicine is an established health care practice. NDs are licensed in 18 states and two U.S. territories and have prescribing rights in 13 states. The DEA grants DEA numbers to NDs with prescribing rights. Additionally, NDs work alongside allopathic doctors in local clinics, including clinics in Billings and Missoula, Montana, and in more than two dozen hospitals nationwide.

COMMENT 8: Several commenters opposed adding the five substances to the formulary because NDs do not have sufficient education and training. Two commenters stated that they are physicians and have seen cases of patients who have been prescribed medications inappropriately or have had medical applications by NDs and have had complications, including a septic joint from a knee injection. One commenter stated that, as an internist, the commenter has seen NDs inappropriately overdose patients with thyroid replacement therapy directly contributing to subsequent atrial fibrillation with heart attack, osteoporosis, and diarrhea.

RESPONSE 8: The board disagrees that licensed NDs lack education and training. See Response 1. Further, licensed NDs have an excellent patient safety record. See Response 1. A person alleging that an ND acted unprofessionally in treating a

patient or failed to meet the generally accepted standards of care may file a complaint with the board under 37-1-308, MCA, and the board may impose disciplinary action under 37-1-312, MCA.

COMMENT 9: One commenter admitted being unfamiliar with naturopathic education and training, but "feels like there is some hostility from their profession about how we overuse medications and it seems every year they want to expand their own formulary."

RESPONSE 9: Montana-licensed NDs are primary health care providers with comprehensive education and training. See Response 1. As explained in Responses 2 and 3, the formulary list is nonexclusive. Specifically listing the five substances is not an expansion of the formulary, but a clarification intended to facilitate the ability of patients to fill prescriptions written by NDs.

COMMENT 10: Several commenters specifically opposed listing insulin or any other diabetic medication, such as metformin, on the formulary. The commenters stated that the use of insulin is part of the training of allopathic and osteopathic medical schools, but the training of NDs does not encompass the treatment of diabetes to the extent necessary to care for diabetes patients who require insulin or other medications.

The commenters stated that allowing insulin to be prescribed by NDs without sufficient training and experience could result in a higher potential for errors, harm patient safety, and even patient death from insulin overdose.

One commenter further stated that many naturally occurring substances are lethal to humans and that "the only people that would benefit from it [listing and prescribing insulin] are the naturopaths, not the general public."

One commenter stated that in all medical decision making, the risks and benefits need to be carefully weighed and that it would have to be a weighty argument indeed to suggest that the increase potential for harm from NDs prescribing insulin was outweighed by the benefit to "our community."

One commenter stated that the board would be moving away from its first priority of protecting the public by permitting naturopaths to prescribe insulin.

One commenter stated that allowing naturopaths to prescribe insulin will mislead patients into thinking that their entire diabetes management has been covered and to "bypass appropriate care for this disease that has significant long term consequences to many organ systems that again naturalpaths [sic] are not trained to monitor."

One commenter stated that, "[a]ny patient who is diabetic and has a need for these drugs should be seeing a real doctor."

RESPONSE 10: Montana-licensed NDs are trained and licensed as primary care providers. See Response 1. As explained previously, NDs have education and training to prescribe insulin and the formulary is a nonexclusive list. See Responses 1, 3, and 6. Moreover, the board notes that NDs know when to function as primary care providers and when to refer patients to a specialist. NDs have excellent patient safety records. See Response 1. For all licensed health care providers, it is

unprofessional conduct under 37-1-316(18), MCA, to perform any treatments or provide services beyond the provider's education, training, and licensure.

COMMENT 11: Several commenters who opposed listing insulin and metformin asserted that naturopaths are not trained to recognize and treat the possible complications. Three commenters stated that insulin overdose results in visits to hospital emergency departments and hospital admissions and, since naturopaths do not have hospital privileges, they will not suffer any of the consequences of poor prescribing practices. One commenter further stated that treating insulin overdose, "requires the training which if there is any in the naturopath community, it is completely unregulated."

RESPONSE 11: Montana-licensed NDs are primary care providers and are trained to recognize and treat possible complications. See Response 1 regarding the education, training, licensing, and patient safety record of NDs. The board believes the commenter makes a gross overgeneralization in stating that because licensed NDs do not have hospital privileges in Montana, there are no adverse consequences for NDs. For all licensed health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform any treatments or provide services beyond the provider's education, training, and licensure.

COMMENT 12: Several commenters opposed adding insulin to the formulary rule because insulin is a very difficult drug to prescribe and manage since it has a very narrow toxic-therapeutic ratio. Diabetic patients must be closely monitored because no two patients are alike in their insulin sensitivity and insulin sensitivity can be affected by an individual patient's exercise, food consumption, body hormones, lifestyle, life stress, and work habits.

The commenters stated that most MDs and DOs defer the regular management of insulin to specialists or endocrinologists who are extensively trained in the use of this hormone.

The commenters stated that insulin, in the context of its clinical use, is a drug and not a natural hormone. One commenter stated that insulin is not one drug because there are many types of insulin, which vary in speed of onset and duration, and therefore a single prescription is not sufficient.

RESPONSE 12: The board acknowledges that insulin prescribing is an exacting and sometimes complicated process. Like other primary care providers, such as MDs and DOs, licensed NDs do refer patients to endocrinologists when necessary. See Responses 1, 3 and 4.

Insulin, like many pharmaceuticals, has been changed, manipulated, and perfected over the years. The formulary identifies types of substances that licensed NDs may administer and prescribe and then lists specific examples. See Response 3. The formulary reflects the legislature's intent that NDs may prescribe substances covered by approved naturopathic colleges and continuing education while providing flexibility through the listing of examples to keep pace with pharmaceutical advances. See Response 3.

Licensed NDs are primary care providers and Montana is underserved by primary care providers. To require a patient who is stable, doing well, monitoring blood sugar levels, and administering medication appropriately, and thereby minimizing the secondary complications of diabetes, to seek treatment from another health care provider to obtain one prescription is not necessary and not consistent with a managed and economical health care model.

COMMENT 13: One individual commenter stated that metronidazole is an antibiotic that could be incorrectly used if the prescriber has not diagnosed the cause of the infection and run susceptibility studies. This commenter further stated that prescribing the wrong drug results in "overprescribing the wrong drug, failure to cure, adverse drug reactions, and waste of money."

RESPONSE 13: Like other primary care physicians, NDs can and do order clinical laboratory tests to identify the cause of an infection to avoid incorrectly prescribing an antimicrobial such as metronidazole. See 37-26-301(4), MCA.

NDs have the requisite education, training, and licensure to prescribe antimicrobials. See Response 1 regarding the education, training, and licensing of NDs. Further, antimicrobials have been listed on the formulary since its inception. As explained in Responses 2 and 3, the formulary list is nonexclusive and the alternative health care formulary committee has reviewed and recommended that metronidazole be specifically listed in the formulary to facilitate the ability of patients to fill prescriptions.

COMMENT 14: One individual opposed adding botox and stated that it is one of the most potent neurotoxins known and has potential to cause severe paralysis if not administered appropriately. The commenter further stated that the claim that botox is a natural substance is only partially substantiated because "all commercially available products are chemically modified to maintain stability and minimize spread of the drug beyond local injection sites." If an ND attempted to produce this toxin and administer it in its natural state without chemical modification, it could spread far beyond the site of local injection and result in respiratory failure and death.

Another individual commenter stated that NDs should not inject botox or Juvederm because they are not trained to treat allergic reactions and other complications from these substances.

RESPONSE 14: The board disagrees. NDs are trained in emergency medicine, biophysics, and chemistry, and are able to recognize and treat allergic reactions. See Response 1 for information regarding the education, training, licensing, and patient safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 15: Several commenters stated that it is inappropriate to base the inclusion of a substance on the formulary list on whether the substance is natural or derived from naturally occurring compounds. Many naturally occurring molecules are dangerous and many synthetic molecules are quite safe and vice versa. The

basis for including substances in the formulary should be whether the practitioner has had adequate training to safely treat patients, including monitoring side effects.

RESPONSE 15: Under 37-26-301, MCA, licensed NDs have authority to prescribe pharmaceuticals with a natural basis and that do not go beyond the scope of substances covered by approved naturopathic colleges or continuing education. NDs are trained to recognize and treat complications and side effects of pharmaceuticals. See Response 1 regarding the education, training, licensure, and patient safety record of NDs.

COMMENT 16: Several commenters stated the current formulary list is overly broad and requested that the formulary list be amended to omit one or more substances including thyroglobulin and opioid or narcotic pain medications. One commenter stated that naturopaths should not be allowed to prescribe beyond over-the-counter herbalism.

RESPONSE 16: Because the proposed rule notice did not include the deletion of any substances and therefore did not provide adequate public notice or the opportunity to comment, the board cannot consider the proposed deletions.

The formulary, including listing the five substances, is appropriate. See Responses 1, 3, and 4 regarding the education, training, licensing, and patient safety record of licensed NDs and the formulary list. The comment that licensed NDs should be limited to over-the-counter herbalism demonstrates remarkable ignorance of the education, training, licensing, and patient safety record of licensed NDs. See Responses 1, 3, 4, 6, and 7.

COMMENT 17: Numerous commenters supported the additions to the formulary list, stating that NDs are licensed primary care providers in Montana and are called on to provide care which sometimes requires these medications.

The commenters stated that NDs attend graduate level naturopathic medical colleges, such as Bastyr University and the National College of Naturopathic Medicine. Naturopathic medical training includes four to five years of didactic work, which includes one year of conventional pharmacology training which is consistent with most medical programs. Additionally, NDs also spend three to four years, in conjunction to didactic work, completing clinical training in an outpatient clinic setting. After becoming licensed in Montana, NDs must complete 15 hours of continuing education annually with at least five hours in pharmacology.

The commenters stated that the landscape of health care is changing and there is a shortage of primary care providers in Montana and the nation. The shortage is being filled by other providers, such as Physician Assistants and Nurse Practitioners. Commenters stated that ND training is more extensive than that of Physician Assistants and Nurse Practitioners who already have full prescriptive rights and are practicing as primary care providers in Montana.

The commenters stated that patients are demanding that they be able to use NDs for their primary care needs. There was a statewide effort requesting the Montana Insurance Commissioner to fully support the implementation of the

Affordable Care Act, provision 2706, which prohibits insurers from discriminating against any licensed providers for services provided within the scope of practice.

RESPONSE 17: The board acknowledges the comments and concurs, noting that the formulary list is not exclusive and including the five substances does not expand the scope of the formulary. See Response 3. Further, licensed NDs are fully trained on proper assessment and diagnosis and know when to function as a primary care provider and when to refer patients to specialists. See Response 1 regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to provide treatment or services beyond the provider's education, training, or licensure.

COMMENT 18: One commenter stated that, historically, there has been a general lack of understanding of the training and skill levels of licensed NDs which "increases the risk of the profession being a victim of ignorance and prejudice. Judging NDs unqualified to prescribe insulin simply represents a judgment based upon a lack of knowledge and information."

RESPONSE 18: The board acknowledges the comment and concurs.

COMMENT 19: One commenter, who completed four years of medical school and a two-year residency prior to being licensed as a Montana ND, supported the additions to the formula. The commenter noted that formal education of NDs includes pharmacology as well as important herb-drug interactions and the professional licensing exam assesses pharmacology knowledge. Further, NDs are required to complete five hours of continuing education in pharmacology annually. The commenter uses "several conventional databases, such as Up To Date, Epocrates, and Medscape, to stay current with pharmacology trends and updates."

RESPONSE 19: The board acknowledges the comment and the commenter's efforts to stay current regarding pharmacology trends and updates.

COMMENT 20: Several commenters supported the formulary additions, stating that Montana-licensed NDs are trained to use hormones, including insulin, and are knowledgeable of the potential problems associated with their use. Montana-licensed NDs are registered with the DEA and are able to prescribe thyroid hormones, estrogen, progesterone, and testosterone. They are aware that insulin must be used with the utmost care and have the training and skill to manage this hormone with their patients.

RESPONSE 20: The board acknowledges the comment and notes that the formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3. Further, licensed NDs are fully trained on proper assessment and diagnosis and know when to function as a primary care provider and when to refer patients to specialists. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA,

to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 21: One commenter supported the formulary additions and stated the number of diabetic patients treated by all providers is increasing and Montana-licensed NDs can prescribe other substances with more potential for risk.

RESPONSE 21: The board acknowledges the comment. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 22: One commenter supported the formulary additions and opined that the amendment is merely a formality because these substances could easily be interpreted to be part of the current formulary.

RESPONSE 22: The board acknowledges the comment and concurs. See Responses 2 and 3 regarding the formulary list.

COMMENT 23: One commenter supporting the additions stated that, as a primary care provider and a naturopathic physician, the commenter provides support and prevention of possible side effects when prescribing medication. The commenter noted insulin is very necessary for Type I and some Type II diabetics, but NDs also focus on the totality of diabetic care to address "the deeper cause of an infection, or prevention of renal failure or HTN in diabetes by early evaluation of renal function and treatment with supplements that promote circulation and prevent advance glycation end products." Additionally, NDs can provide education and assistance regarding diet and lifestyle, as well as nutraceuticals, to reduce the need for insulin.

RESPONSE 23: The board acknowledges the comment and concurs. See response 1 for information regarding the education, training, licensing, and patient safety record of NDs.

COMMENT 24: A commenter supporting the formulary additions stated that medical training of NDs, like all primary care providers, includes the steps in assessing, diagnosing, and treating diseases, and also understanding the risks of treatments. As part of primary care education, both ND and MD students are trained to understand and know medical standards of care for acute and chronic diseases, including diabetes.

The commenter further opined that licensed NDs know that the medical management of diabetes includes risk assessments of both physical and biological systems. "Risk assessment of physical systems includes, but is not limited to, the evaluation of the cardiovascular, renal/kidney, ocular/eye, and (autonomic) nerve systems. Biological systems risk assessments include evaluation for ketoacidosis and associated chemistry changes (hyperosmolar hyperglycemic state), which represent serious and potentially life-threatening biological imbalances."

Further, licensed NDs, like all primary care providers, must refer patients to indicated and appropriate specialists, ER, or hospital when clinical assessments

reveal a potential urgent or chronic complication risk. "Naturopathic physicians are not exempt from this requirement and are as liable as any physician or practitioner if they do not follow through on these obligations."

RESPONSE 24: The board acknowledges the comment and concurs. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 25: One commenter, who has reviewed an ND's patient charts and consulted with an ND regarding cases and particularly endocrine disorders, supported the formulary additions. The commenter found the ND to be conscientious and effective in caring for diabetic patients, including using appropriate laboratory tests to monitor them and competently prescribing medications such as insulin. The commenter stated that the ND is an outstanding clinician, well informed, knows the scope of practice, and routinely seeks specialist advice and or referral when appropriate. The commenter would also recommend the ND to a family member who required a primary care physician to care for their diabetes mellitus.

RESPONSE 25: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 26: One commenter supported the formulary additions and stated that NDs attract and work with a higher percentage of self-motivated and compliant individuals compared to the average primary care provider in the United States. This patient population is willing to work on and through life-style changes in the context of treating diabetes. NDs are required to use and adjust insulin or insulin affecting medications in treating diabetic patients in conjunction with prescribing diet, nutritional, and/or exercise programs to lower an individual patient's insulin requirements.

RESPONSE 26: The board acknowledges the comment and concurs. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 27: A commenter supporting the formulary additions stated that all "physicians, regardless of training and licensing, e.g., Naturopathic, Medical Osteopathic, have a professional obligation to be well versed in particular pharmaceutical drugs before they either prescribe and/or administer them to

patients." The commenter further stated that Montana-licensed NDs "understand this obligation and are well trained to fulfill it."

RESPONSE 27: The board acknowledges the comment and concurs. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. For all health care providers, it is unprofessional conduct under 37-1-316(18), MCA, to perform treatments or provide services beyond the provider's education, training, or licensure.

COMMENT 28: Several commenters supporting the formulary additions stated that many patients choose to see NDs for their primary care needs, and the Affordable Care Act recognizes patient choice in health care and recognizes naturopathic physicians as primary care providers. Further, denying the addition of these drugs to the formulary would be denying Montanans a choice in health care.

RESPONSE 28: The board acknowledges the comment and concurs. See Response 1 for information regarding the education, training, licensing, and safety record of NDs.

COMMENT 29: One commenter supporting the formulary additions opined that MDs are regularly visited by drug company representatives and thus receive their continuing education by default. NDs are required to complete five hours of continuing education annually in pharmacology.

RESPONSE 29: The board acknowledges the comment and agrees that NDs are required to complete five hours of continuing education annually in pharmacology. See ARM 24.111.2102.

COMMENT 30: Two commenters supported the formulary additions and indicated that the pharmacology education of NDs is extensive because it includes drugs and alternative treatments. Further, most of the population uses vitamins and herbs, which NDs excel in prescribing and are well informed regarding possible interactions based on the pharmacology training received in naturopathic college and the annual continuing education requirements for licensure. The commenter noted that the last seminar (by the association) included the use of insulin and the management of patients who are insulin dependent.

RESPONSE 30: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 31: Several commenters specifically supported adding insulin and metronidazole to the formulary. The commenters stated that Montana-licensed NDs are trained and licensed as primary care providers and do not prescribe pharmaceuticals unless there is a great necessity for them.

RESPONSE 31: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 32: One individual supported the formulary additions and asserted that it regularly takes a month for a patient to get an appointment with an MD, but patients who see an ND can get the care they need without a second visit to an MD for the same problem.

RESPONSE 32: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 33: One commenter supporting the additions to the formulary stated that it creates a hardship for patients and chaos in the health care system if an ND's primary care patients have to find another doctor to prescribe medication.

RESPONSE 33: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 34: One commenter supported the formulary additions and stated that future naturopathic prescribing rights discussions would be appropriate to focus on eliminating prescribing restrictions in regard to "all basic general practice-level medications." Primary care providers should be able to provide the best indicated medications in the best interest of their patients. The commenter noted that while NDs prefer using minimally invasive treatments for health and healing purposes, "there are times and (acute) situations where specific prescription medications are safer or more appropriate" and "formulary and prescribing restrictions create unnecessary obstacles in providing the best medicine that is in the best interest of a patient."

RESPONSE 34: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 35: Numerous individuals, who receive primary care from NDs, supported the formulary additions. These commenters want their NDs to be able to provide full and complete care that is consistent with their training and asserted that denying the addition of these substances to the formulary list has the effect of denying patients their choice of primary care providers.

One commenter, who had previously seen many medical doctors and specialists as a "multiple medical condition" patient, is now being treated by an ND

as a whole person with a significant positive impact on the commenter's health. The commenter is currently searching for a medical doctor, in addition to her ND, to get prescriptions refilled and stated that "[i]t is unfair for myself, and patients like me, to have to pay visits to more than one physician when naturopathic physicians could, and have the training to, prescribe all of these medications."

RESPONSE 35: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs.

COMMENT 36: As a young adult, one commenter had a hemoglobin A1c result of around 11 and was diagnosed with Type 1 diabetes by the ND providing primary care. The ND educated intensively on diabetes over several days in two to three hour appointments, taught the patient how to monitor blood sugar (eight to ten times per day), prescribed slow acting and fast acting insulin and instructed on when and how to use them, and warned that too much insulin can kill you. The ND had the patient maintain a log of the food eaten and blood sugar test results. The ND prescribed the commenter to cut carbohydrates and sugars as much as possible and eat three meals a day, "referencing that rationale that the less insulin you have to take to cover carbohydrates, the less room there is for error in insulin dosage (once again, too much insulin can kill you)." The ND also prescribed a consistent muscle-building workout three times a week. Three months after being diagnosed, the patient stated that his hemoglobin A1c was normal.

The patient stated that, for the last two years, his ND has "prescribed and administered a VERY effective insulin treatment of my Type 1 diabetes," taught the commenter everything needed to know about being a diabetic, and provided continued support to this day with checkups and conversations about the patient's progress. (Emphasis in the original.) The patient stated that the ND is the patient's diabetes doctor and that if the ND was not able to prescribe insulin, the ND would not have been able to provide complete and lifesaving treatment.

RESPONSE 36: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 37: One commenter began treating with an ND last year after months of seeing several medical doctors who ran numerous and expensive tests, including blood tests, tests for HIV and MS, and MRIs, but failed to make a diagnosis. Instead, the patient was only treated for a few symptoms. Based on a Western blot test showing 7 out of 12 bands being positive, the ND diagnosed Lyme disease and prescribed a treatment of antibiotics and herbs. The patient appreciated that his ND could prescribe the necessary medication.

RESPONSE 37: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 38: A commenter with Type 1 diabetes for over 40 years stated that two NDs have been more helpful in controlling the commenter's diabetes than any MDs. The patient stated NDs are trained to use medications, are knowledgeable about interactions, and need to be able to prescribe medications including insulin. The patient stated that the legislature made NDs primary care providers and NDs need to have the tools to be primary care providers.

RESPONSE 38: The board acknowledges the comment. See Response 1 for information regarding the education, training, licensing, and safety record of NDs. The formulary list is not exclusive and specifically listing the five substances does not expand the scope of the formulary. See Response 3.

COMMENT 39: One individual commenter stated that anyone can get insulin from a retail pharmacy without a prescription in Montana.

RESPONSE 39: The board notes that only a few older, short-acting insulin products are available without a prescription and that newer and longer acting insulin products now require a prescription.

NEW RULE I MILITARY TRAINING OR EXPERIENCE:

COMMENT 40: One commenter indicated that certain military personnel, such as reservists and national guardsmen who have never been activated, do not receive a DD 214 military discharge document. The commenter requested that the proposed rule be revised to allow the board to consider other evidence of military discharge in addition to or in lieu of a DD 214 form.

RESPONSE 40: The board agrees with the commenter and is amending the rule to provide that evidence of military discharge may be established through a DD 214 form or other discharge document.

4. The board has amended ARM 24.111.511 exactly as proposed.

5. The board has adopted NEW RULE I (ARM 24.111.412) with the following changes, stricken matter interlined, new matter underlined:

NEW RULE I MILITARY TRAINING OR EXPERIENCE (1) and (2) remain as proposed.

(3) An applicant must submit satisfactory evidence of receiving military training, service, or education that is equivalent to relevant licensure requirements for direct-entry midwives and naturopathic physicians. ~~At a minimum, satisfactory~~ Satisfactory evidence ~~shall~~ may include:

(a) a copy of the applicant's military discharge document (DD 214 or other discharge documentation);

(b) through (4) remain as proposed.

BOARD OF ALTERNATIVE HEALTH CARE
MARY ANN BROWN, DEM, CHAIRPERSON

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ PAM BUCY
Pam Bucy, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 8, 2014